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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,679	12/01/2003	Erning Xia	P03294	2369

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	**PAPER NUMBER**
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/724,679	XIA ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/11/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 is drawn to a method of preventing deposition of lipids and proteins on a contact lens while worn on the eye but in the last two lines of the claim it states that the contact lens is inserted in the eye, implying the contact lens was in fact taken off the eye, therefore the contact cannot be considered as being worn during the cleaning process.

Claims 2 and 23 contains the trademark/trade names Pluronic and Tetronic. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of **35 U.S.C. 112**, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe one or more nonionic polyether surfactants and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Xia (US 6,369,112 B1).

Xia teaches disinfecting and cleaning solutions for contact lenses comprised of A) about 0.0003 to about 0.5% of biguanidine antimicrobial B) 0.01-10% poloxamine surfactant such as Tetronic C) a further surfactant such as tween-20 (satisifies HLB greater than 18, as recited in applicants specification [0028]), D) phosphate and borate buffers and E) sequestering agents such as EDTA. See col 2 lin 65-col 9 lin 35 and examples.

Claims 1-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellis et al. (US 5,405,878).

Ellis teaches contact lens cleaning solutions containing 0.00001 to about 5% antimicrobial agent and about 0.001 to about 5% of at least one surface active agent selected from poloxamers such as Pluronic and Tween-20. See abstract, col 1 lin 5-61, col 3 lin 10- col 5 lin 53. The contact lens solution further comprised buffers such as borates, phosphates and citrates as well as chelating agents such as EDTA.

Claims 1-6,8-16,18-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Krezanoski et al. (US 4,046,706, cited by applicants).

Krezanoski teaches a composition for cleaning contact lenses, the composition comprises 0.01 to about 40% of a Pluronic copolymer, ethyl or isopropyl alcohol, a chelating agent and phosphate and borate salts. See abstract, col 4 lin 43-col 10 lin 36 and examples.

Claims 1-5,7-14,16-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Winterton (EP 0 439,429 A2, cited by applicants).

Winterton teaches a contact lens conditioning solution containing a non-ionic surfactant such as Tetronic and Pluronics up to 1%, hydrogen peroxide, additional surfactants such as Tween-20 and buffering agents such as phosphates or borates. See pag 3 lin 1-pag 5 lin 25.

Claims 1-5,7-14,16-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Winterton (EP 0 524,150 A2, cited by applicants).

Winterton teaches a contact lens conditioning solution containing a non-ionic surfactant such as Tetronic and Pluronics up to 1%, 3% hydrogen peroxide, additional surfactants such as Tween-20 and buffering agents such as phosphates or borates. See pag 2 lin 1-pag 5 lin 14.

Claims 1-6,8-16,18-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Vigh (WO 95/01414, cited by applicants).

Vigh teaches a solution for cleaning, disinfecting, and rinsing of contact lenses by a combination of 0.1-1.0% of a non-ionic surfactant (including Pluronics) and 0.1 to about 1.0% of an antimicrobial triquarternary phosphate ester. See pag 3 lin 1-col 10 lin

lin 2 and examples. The solution further comprised buffers such as sodium borate as well as chelating agents.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vigh (WO 95/01414, cited by applicants) in view of Winterton (EP 0 439,429 A2 or EP 0 524,150 A2, disclosed by applicants).

Vigh is disclosed above. Vigh does not disclose the use of a second surfactant with an HLB higher than 18 such as Tween-20.

The Winterton references are disclosed above. Winterton is used to primarily show that mixtures of surfactants such as Tetronic or Pluronics with other surfactants such as polysorbates eg Tween-20 was already well known in the art to be useful in solutions intended for cleaning/disinfecting contact lenses.

It would have been prime facie obvious at the time of the invention to a person of ordinary skill in the art to modify the surfactants disclosed in Vigh and add the Tetronic or Pluronics in combination with polysorbates as disclosed within the Winteron references. It is generally considered to be prime facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of conventional components of a contact lens cleaning/disinfecting solution. The advantage of using polysorbates in contact lens solutions as disclosed in the Winterton references is to prevent agglomeration of oils on a lens in the eye as is common among patients who

wear eye makeup. It therefore follows that the instant claims define prime facie obvious subject matter.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 8-14,18-23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims1-19 of U.S. Patent No. 6,369,112 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because each claims a contact solution comprising an anti-microbial, a non-ioinic surfactant comprising PEO-PPO blocks and a buffer such as a borate buffer.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER